REMARKS

Claims 1 to 35, 38 to 40, and 71 to 111 are in the application. The claims have all been amended to correct various typographical errors, or to better clarify the present invention. No new matter is believed added.

Applicants thank the Examiner for the interview of 8 December 2005 in the above noted application. The amendments are believed to distinguish the extruded and molded capsule shells and subunits of the present invention from conventional capsule components which are coated with various polymers. The Examiner is requested to contact the undersigned at the number indicated below if there are any questions or comments regarding these amendments.

It has come to Applicants attention that there are several errors in the Brief Description of the Drawings. The information presented for Figure 3, on page 6, actually corresponds to the drawing listed as Figure 5. The information presented for Figure 4, page 6, actually corresponds to the drawing listed as Figure 4.

The Figure 3 drawing shows a picture of an E100 shell and subunit, and does not correspond to any description listed in the Brief Description of the Drawings section, and should be ignored.

The Brief Description of the Drawings, Figure 5, page 6 describes a dissolution profile for an E100 composition. No drawing having this dissolution profile appears in the Figures. To better clarify the record, Applicants submit with this response a copy of an E100 composition a dissolution profile corresponding to the description in Figure 5, so that the record is complete.

Rejection of Claims under 35 USC §103

Claims 1 to 35, 38 to 41 and 71 to 111 are rejected under 35 U.S.C. § 103(a) as being obvious over Hatano et al. US Patent No. 6,309,666 ('666) in view of Lehmann et al. US Patent No. 5,705,189 ('189). Applicants respectfully traverse this rejection.

Pursuant to the Interview of 8 December 2005 Applicants have amended the claims directed to a pharmaceutical composition to more specifically point out and distinctly claim the invention. As discussed previously in Applicants response of 11 July 2005 (incorporated herein by reference) the capsule shell (as well as the linkers and subunits) have a wall, or a shell which wall or shell composed of the composition as claimed. This is clearly in direct contrast to the teachings of Hatano which produce "coated capsule compositions comprising a hard outer shell (See Abstract)". Suitable materials for the outer shell include methacrylate co-polymers and acrylic copolymers. *See* Office Action, 11 January 2005 at page 3, ¶ 2.

The present invention, in contrast to the disclosure of Hatano et al. does not use an enteric polymer for the same purpose, i.e. the overcoating a capsule shell. The present invention utilizes at least one particular polymer in a pharmaceutically acceptable composition to actually make the walls of a capsule shell (which shells in the Hatano et al. disclosure overcoated by a polymer).

The particular polymer used herein is a copolymer of methyl acrylate, methyl methacrylate and methacrylic acid with a molar ratio of monomer units represented as 7:3:1. This copolymer is also known as Eudragit 4135F, Eudragit FS100, or 4155F (Eudragit FSPO). Claim 1 has been amended to characterize the polymer by its chemical composition, rather than by its tradename.

In the prior Office Action, the Examiner acknowledged that Hatano does not disclose a molding process for making "hard outer capsule shells". *See* July 11, 2005 Office Action, at page 3, ¶3. The Office seeked to fill this gap with the Lehman et al. reference.

Specifically, the Office looks to Lehman for the alleged disclosure of a process for producing "acrylic and/or methacrylic articles, such as capsules, by molding" *See* July 11,

2005 Office Action, at page 3, ¶4. The Office, in the present rejection, at page 3, 3rd paragraph discusses Applicants arguments, and that "it is unclear how the applicant has arrived at the conclusion that the reference would teach one of ordinary skill in the art that additional excipients are not needed, as the reference clearly states that a variety of excipients can be incorporated into the disclosed compositions, as one of ordinary skill in the art deems suitable for a particular function".

As noted previously, the Lehmann et al. patent discloses various compositions of *anionic* methacrylates including the polymer 4135F. The claims of the Lehmann et al. patent, do not cover the disclosed E2 or the E3 emulsions. The disclosure does not indicate that this particular emulsion was suitable for molding.

The thermostability, melt flow characteristics, and apparent shear viscosity of the compositions as described in Lehman et al. '189 differ within themselves and from the polymer 4135F, see for instance Examples 1, and 7 to 9 as well as Figures 1 and 2.

The present invention requires (Claim 1) the addition of a dissolution modifying excipient (DME) present in amounts of 2.5 to 70% by weight. DME's are described in Applicants specification on page 27, lines 25 to 35 and page 28, lines 1 to 34. Claims 11 to 13 require the DME to be a swellable solid, such as HPMC, or HPC. In contrast, the '189 patent does not disclose the use of a DME in their compositions.

The '189 Lehmann patent also does not disclose use of stearyl alcohol, talc, magnesium stearate, silicon dioxide, amorphous silicic acid, or fumed silica or combinations thereof as alternative lubricants. Claims 9, and 10 as claimed herein specifically require use of stearyl alcohol as a lubricant.

The '189 Lehmann patent also does not disclose the use of surfactants in their compositions, as disclosed in Applicants specification on page 26, lines 15 to 37, and page 27, lines 1 to 3, and as claimed in Claims 3, 4, 5, 6, and 18 to 21.

Applicants Claims 14 and 15 include in the composition non-reducing sugars, water soluble fillers and disintegrants. Claims 16 and 17 are directed to various combinations of these

agents. The Lehman '189 patent also does not disclose nor suggest inclusion of such agents.

Further, there is no suggestion in the '189 patent to incorporate a "super disintegrant" such as croscarmellose sodium, copovidone, or sodium starch glycollate (Claims 14, and 16). Super disintegrants are typically utilized in the pharmaceutical industry for compressed tablet formulations (to aid in dissolution), not in the structural wall of a capsule shell.

There is no motivation present in the Lehman patent to direct the skilled artisan to include a DME, let alone a disintegrant, etc. in the molding composition. The Hatano et al. '666 patent, not only does not direct the skilled artisan to utilize a thermoplastic polymers (to overcoat capsule shells), it does not direct the skilled artisan to choose such as polymer having these characteristics, and does not use additives and excipients to achieve the same desired properties as Applicants, i.e. a composition which be molded. Hatano et al. would not look to the disclosure of Lehman et al. to achieve these characteristics. As a result, the Office has failed to make out a *prima facie* case of obviousness.

In looking at the requirements for maintaining a *prima facie* case of obviousness, one is the reasonable expectation of success. The Office has provided no basis for this requirement. Lehman which does discuss the need for a plasticizer and a mold-releasing agent, does not provide any values for the recited concentrations of any additional excipients, i.e. stearyl alcohol, dissolution modifying excipients, and superdisintegrants, which appear in Applicants specification and claims. As shown in the Interview, the polymer 4135 is basically not moldable without the inclusion of Applicants additional agents. It has long been settled that for obviousness purposes, the reasonable expectation of success must not come from the applicant's own disclosures, and consequently these two references in combination fail to provide a reasonable expectation of success.

In view of the Interview, remarks, and amendments herein, it is believed that there is no longer the necessity for a showing of unexpected results to obviate the obviousness rejection. Because there is no *prima facie* case of obviousness in view of Hatano et al., taken with Lehman et al., Applicants do not bear the burden of making such a showing at this juncture. Having established that the Office has failed to set forth a *prima facie* case of obviousness, Applicants respectfully request the withdrawal of the §103 rejection to the claims and issuance of a Notice of Allowance.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. It is not believed that this paper should cause any additional fees or charges to be required, other than expressly provided for already. However, if this is not the case the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,

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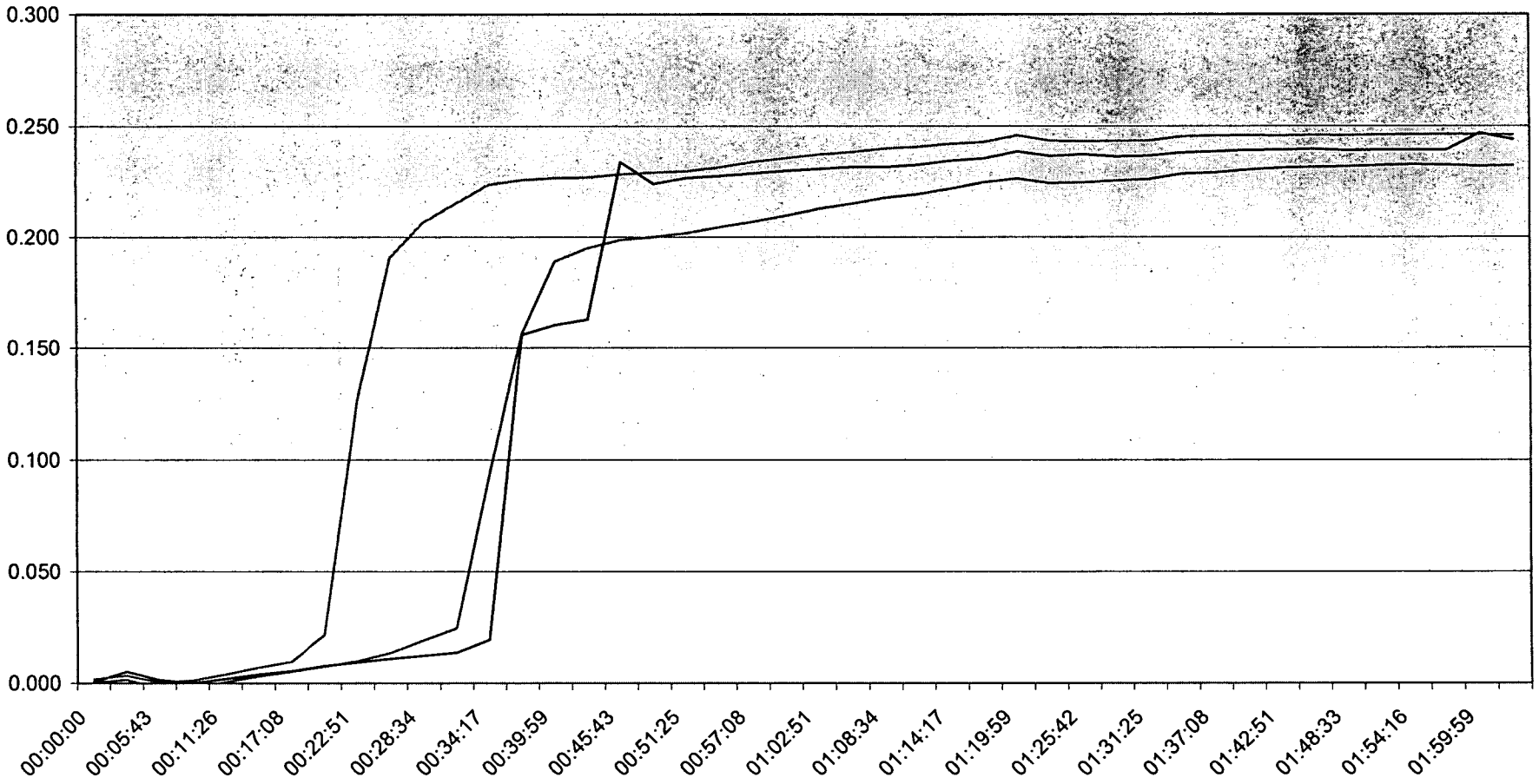
Dissolution of a Compound in SGF (pH 1.2) from E100 + 20% PolyOx WSRN80 + 5% Stearyl Alcohol 0.5mm, welded to Eudragit 4135F components



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